REMARKS

Claims 1-13, 21, 22, 32-40 and 78-104 are now pending. By this Amendment, claims 1-13, 21, 22 and 32-40 are amended; claims 14-20, 23-31, 41-71, 73 and 74 are canceled; and claims 78-104 are added. Support for the amendments can be found at, for example, the original claims; page 4, lines 15-17; page 8, line 4; and page 9, lines 27-38.

Included with the Office Action are Forms PTO-1449 acknowledging consideration of some of the references cited therein. Attached is a Request for Acknowledgment of Consideration of Disclosed Information requesting acknowledgement of consideration of references disclosed in these Forms PTO-1449 that have not been initialed.

Claims 1-13, 18-22 and 32-40 are rejected under 35 U.S.C. §112, second paragraph, for allegedly omitting essential steps. Claims 1 and 32 are amended herein to recite a detection method that results in the detection of superantigen activity. Therefore, the rejection should be withdrawn.

Claims 1, 13, 18-22 and 32-40 are rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite. The phrase "characterized in that" has been deleted from the claims. With regard to the term "superantigen," Applicants respectfully traverse the rejection.

The present claims are directed to a method for detecting superantigen activity in a biological sample. As noted in the Office Action, the specification indicates that superantigen-like molecules having properties close to certain effects that superantigens are known to have are included in the term "superantigen." Thus, claims 1 and 32 include methods in which the majority expansion of lymphocytes bearing a particular determinant or majority loss of lymphocytes bearing a particular determinant indicates the presence of a molecule that, although technically is not a superantigen, has properties close to that of a superantigen. However, contrary to the Office Action, these properties are not undefined. Instead, the specification clearly indicates that superantigens are:

> molecules capable of binding to class II major histocompatibility complex (MHC) molecules and to peptide sequences characteristic of certain T-cell receptor families (Vβ). These superantigens activate a large number of T clones, independently of the antigenic peptide recognized by their TCR (T-cell receptor) in association with the MHC of the antigen-presenting cell. The consequence of this activation is a polyclonal proliferation or an induction of anergy, or even of apoptosis, in the T-lymphocyte population carrying this Vβ.

Thus, the properties of superantigens are well characterized in the specification.

In addition, since the present claims are not directed to superantigens per se, but are instead directed to a method of detecting superantigen activity, the claims further define the superantigen activity. In particular, the claims indicate that the superantigen activity is associated with a majority expansion of lymphocytes bearing a particular determinant or a majority loss of lymphocytes bearing a particular determinant. Thus, the superantigen-like activity encompassed by claims 1 and 32 clearly encompasses a majority expansion or loss of lymphocytes bearing a particular determinant.

The specification clearly defines a superantigen. As such, one of ordinary skill in the art would have been able to recognize a molecule that is superantigen-like. Therefore, the rejection should be reconsidered and withdrawn.

Claims 1-13, 18-22 and 32-40 are rejected under 35 U.S.C. §112, first paragraph, for allegedly not being enabling. Claims 1 and 32 have been amended to recite method steps that result in the detection of superantigen activity. It is respectfully submitted that these method steps are enabled by the present specification. Therefore, the rejection should be reconsidered and withdrawn.

Claims 37-40 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description in the specification. Applicants respectfully traverse the rejection.

In University of California v. Eli Lilly & Co., the Federal Circuit indicated that "a written description of an invention involving a chemical genus...requires a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to

distinguish it for other materials." 43 USPQ2d 1398, 1405 (Fed. Cir. 1997) (emphasis added). Claims 37 and 38 have each been amended to recite that the peptide fragment is at least six amino acids in length. The specification clearly describes the use of fragments of SEQ ID NO: 2 and SEQ ID NO: 1 in the claimed method. In addition, given the description of the sequences of SEQ ID NO: 2 and of SEQ ID NO: 1, one of ordinary skill in the art would have been able to distinguish a fragment of one of these two sequences from sequences that are not encompassed by the claims. Thus, the specification clearly provides written description of these sequences. Therefore, the written description rejection should be reconsidered and withdrawn.

Claims 1-13, 18-22 and 32-40 are rejected under 35 U.S.C. §103 over WO 99/05527 in view of U.S. Patent No. 5,336,598 to Kotzin et al., the 1998 Abstract by Komurian-Pradel et al., and the 1995 article by Herrmann et al. Applicants respectfully traverse the rejection.

WO 99/05527 describes a process for diagnosis of a human autoimmune disease associated with human endogenous retrovirus (HERV) having superantigen (SAg) activity. However, WO 99/05527 does not teach or suggest that multiple sclerosis is associated with a human endogenous retrovirus having superantigen activity. In particular, WO 99/05527 does not teach or suggest that the *env* gene of MSRV-1 induces superantigen activity. In fact, WO 99/05527 specifically indicates that, with regard to the retrovirus isolated from cells of multiple sclerosis, "[n]o superantigen activity of the retrovirus has been identified."

The secondary references do not overcome the deficiencies of WO 99/05527. In particular, none of the secondary references teach or suggest that a retrovirus associated with multiple sclerosis, particularly MSRV-1, has superantigen activity.

The cited references do not teach or suggest the claimed methods. Therefore the §103 rejection should be reconsidered and withdrawn.

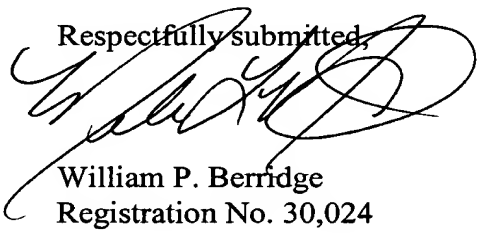
Claims 78-104 have been added to further define the invention. Dependent claims 78-102 are patentable for at least the reasons discussed above.

Claims 103 and 104 each recite a method for detecting multiple sclerosis or a condition associated with multiple sclerosis, in a biological sample from a patient having or suspected of having multiple sclerosis or having a risk for developing multiple sclerosis. Each method involves determining an amount of expansion or loss of lymphocytes bearing a Vβ determinate. However, none of the cited references teach or suggest that an expansion or loss of lymphocytes bearing a Vβ determinate is associated with multiple sclerosis. Thus, the cited references do not render claims 103 and 104 obvious.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-13, 21, 22, 32-40 and 78-104 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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WPB:MLM/jam

Attachment:
Request for Acknowledgment of
Consideration of Disclosed Information

Date: May 27, 2005

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